NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Point Biopharma USA Inc. 4850 W. 78th St. Indianapolis, IN 46268 REPORT NUMBER(S) 2021001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-39229	13-35593-01	August 19, 2021

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Luis Nieves Folch	Luis A. Nieves Folch Digitally signed by Luis A. Nieves Folch Date: 2021.09.01 13:40:36 -05'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.09.07 14:51:33 -05'00'	

From: Nieves Folch, Luis
To: Todd Hockemeyer
Subject: POINT Biopharma NRC 591
Date: Thursday, September 09, 2021 10:23:00 AM
Attachments: Point Biopharma 591M(1)mk.pdf

Dear Mr. Hockemeyer

Attach is the clear 591 report for the inspection conducted on August 19, 2021. At this point there is no further actions on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this message will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.
Please feel free to contact me if you have any questions regarding this correspondence.

Thank you,

Luis Nieves
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Office: (630) 829-9571
Fax: (630) 515-1259

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Point Biopharma USA Inc.	030-39229	13-35593-01

4. Report Number(s):	5. Date(s) of Inspection:
2021001	August 19, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Luis Nieves	03620	5	87126

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Todd Hockemeyer	thockemeyer@pointbiopharma.com	317-417-2860

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☑ Initial	☑ Main Office ☐ Field Office	August 19, 2026
☐ Routine ☑ Announced	☐ Temporary Job Site ☐ Remote	☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced		☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced, initial inspection of an R&D facility at the moment, with goals of becoming a radiopharmacy that will distribute unit doses of Lutetium-177 (Lu-177). At the time of the inspection, the licensee's facility was still under construction but a handful of laboratories had been finished and were being used for research, testing of new equipment, and developing procedures.

The licensee intentions are to control every aspect of the production of Lu-177 in-house except for the irradiation process of the material which needs to take place in a reactor. The licensee will received stable (non-radioactive) Ytterbium-176 (Yb-176) in powder form, from an affiliated company in Canada. The licensee will then manufacture a target made of glass and fill it with Yb-176 and send it offsite to get irradiated. After irradiation, the target will contain the radioactive Yb-177 isotope, which decays to Lu-177. The licensee will then process the target to separate the desired Lu-177 from the remaining Yb-176. All of these processes--except the irradiation---will occur inside of shielded hot cells. The licensee will then dispense unit doses and package them for shipping to medical facilities.

PERFOMANCE OBSERVATIONS

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector verified multiple safety equipment, such as survey meters and radiation area monitoring devices, to make sure they were operable and calibrated. The licensee's staff also demonstrated the implementation of procedures for receiving material, processing material, waste handling, shipping of material, QC of material, air effluent monitoring, and bioassays for personnel. Through these observations, demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspector reviewed a selection of records, including inventory, survey meter calibration certificates, hazmat training records, and dosimetry reports.

No violations of NRC requirements were identified as a result of this inspection.